October 18, 2024

Coloplast Corp.
Jennifer Mrkvicka
Principal Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, MN 55411

Re: K242473
Trade/Device Name: Altis Single Incision Sling System (519650); Aris Transobturator Sling System (519551); Supris Retropubic Sling System (519562)
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH, OTN
Dated: August 20, 2024
Received: August 20, 2024

Dear Jennifer Mrkvicka:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242473

Device Name

Altis Single Incision Sling System (519650);
Aris Transobturator Sling System (519551);
Supris Retropubic Sling System (519562)

Indications for Use *(Describe)*

The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

The Aris Transobturator Kit consists of the Aris implantable midurethral support sling and disposable introducers. The Aris sling and introducers are indicated for the surgical treatment of all types of stress urinary incontinence (SUI) and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The Supris Retropubic Kit consists of the Supris implantable midurethral support sling and disposable introducers for placement using a “top-down” or “bottom-up” retropubic surgical approach. The Supris sling and introducers are indicated for the surgical treatment of female stress urinary incontinence (SUI), resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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2.03 510(k) SUMMARY

I. SUBMITTER

510(K) Owner's Name: Coloplast A/S

Legal Manufacturer Address: Holtedam 1
3050 Humlebaek, Denmark

Phone/Fax/Email: Phone: (612) 707-5062
Email: usjmrk@coloplast.com

Name of Contact Person: Jennifer Mrkvicka
Principle Regulatory Affairs Specialist

Address/Contact: 1601 West River Road North
Minneapolis, MN 55411

Date Prepared: October 17, 2024

II. DEVICES

Trade or Proprietary Name: Altis® Single Incision Sling System
Common/Usual Name: Surgical Mesh
Classification Name: Mesh, Surgical
Regulation Number: 21 CFR 878.3300
Product Code: PAH
Device Class: II
Review Panel: Gastroenterology/Urology

Trade or Proprietary Name: Aris® Transobturator Sling System
Common/Usual Name: Surgical Mesh
Classification Name: Mesh, Surgical
Regulation Number: 21 CFR 878.3300
Product Code: OTN
Device Class: II
Review Panel: Gastroenterology/Urology

Trade or Proprietary Name: Supris® Retropubic Sling System
Common/Usual Name: Surgical Mesh
Classification Name: Mesh, Surgical
Regulation Number: 21 CFR 878.3300
Product Code: OTN
Device Class: II
Review Panel: Gastroenterology/Urology

III. PREDICATE DEVICES

For the purposes of establishing substantial equivalence, the proposed Altis Single Incision Sling System, Aris Transobturator Sling System, and Supris Retropubic Sling System were compared to the predicate devices shown in the table below. The predicate devices have not been subject to a design-related recall.

	Primary Predicate (Predicate A)	**Secondary Predicate (Predicate B)**	**Tertiary Predicate (Predicate C)**
Device Trade Name	Altis Single Incision Sling System	Aris Transobturator Sling System	Supris Retropubic Sling System
Regulation Name	Surgical Mesh	Surgical Mesh	Surgical Mesh
Regulation Number	21 CFR §878.3300	21 CFR §878.3300	21 CFR §878.3300
Classification	Class II	Class II	Class II
Product Code	PAH	OTN	OTN
510(k) Submitter/Holder:	Coloplast A/S	Coloplast A/S	Coloplast A/S
510(k) #/ Clearance Date	K221874 Cleared 02/15/2023	K050148 Cleared 03/09/2005	K111233 Cleared 06/24/2011

No reference devices were used in this submission.

IV. DEVICE DESCRIPTIONS

Altis Single Incision Sling System

The Coloplast Altis Single Incision Sling (SIS) System includes one implantable single incision midurethral sling and two Altis introducer needles. The Altis Single Incision Sling System is provided sterile (ethylene oxide sterilization) and is for single use only.

The Altis Single Incision Sling is an implantable, synthetic, knitted, low-elasticity, monofilament polypropylene, single incision midurethral sling. The mesh sling body measures approximately 7.75 cm long by 1.1cm wide. The Altis sling assembly is connected on each end to an anchor. One end of the sling assembly is connected to a short length of USP size 1 polypropylene monofilament suture connected to a static (non-tensioning) polypropylene anchor. The other end of the sling connects to a longer length of suture with a dynamic (tensioning) polypropylene/polyurethane anchor. The dynamic anchor is intended to allow intraoperative adjustment and tensioning of the sling, resulting in urethral support during instances of increased abdominal pressure, thereby preventing urine leakage. The Altis sling is non-absorbable and is intended to be permanent.

The Altis introducers are helical-type instruments (one left, one right), used to assist in the surgical placement of the Altis Single Incision Sling using a transobturator technique, via a single incision vaginal approach. The introducers are manufactured from polycarbonate (handles) and medical grade stainless steel (needles). These introducers are only to be used with the Altis Single Incision Sling System in accordance with the Instructions for Use.

Aris Transobturator Sling System

The Coloplast Aris Transobturator Sling System includes an implantable midurethral sling and disposable introducer needles. The Aris sling and Aris introducers are provided sterile (ethylene oxide sterilization) and are for single use only.

The Aris sling is a synthetic, knitted, low-elasticity, midurethral sling made from monofilament polypropylene. The Aris sling is non-absorbable and intended to be permanently implanted.

Aris introducers (helical pair and flat curve) are instruments used to assist in the correct surgical placement of the Aris sling via the transobturator approach. The introducers are manufactured from polycarbonate (handles) and medical grade stainless steel (needles). These introducers are only to be used with the Aris sling.

Supris Retropubic Sling System

The Coloplast Supris Retropubic Sling System includes an implantable midurethral sling and disposable introducer needles. The Supris sling and Supris introducers are provided sterile (ethylene oxide sterilization) and are for single use only.

The Supris sling is a synthetic, knitted, low-elasticity, midurethral sling made from monofilament polypropylene. The Supris sling is non-absorbable and intended to be permanently implanted.

The Supris introducers are instruments used to assist in the correct surgical placement of the Supris sling via a retropubic approach. The introducers are manufactured from polycarbonate (handles) and medical grade stainless steel (needles). These introducers are only to be used with the Supris sling.

V. INDICATIONS FOR USE

The Altis Single Incision Sling System, Aris Transobturator Sling System, and Supris Retropubic Sling System have the same indications for use as their respective predicate device:

Altis Single Incision Sling System:

The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Aris Transobturator Sling System:

The Aris Transobturator Kit consists of the Aris implantable midurethral support sling and disposable introducers. The Aris sling and introducers are indicated for the surgical treatment of all types of stress urinary incontinence (SUI) and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Supris Retropubic Sling System:

The Supris Retropubic Kit consists of the Supris implantable midurethral support sling and disposable introducers for placement using a "top-down" or "bottom-up" retropubic surgical approach. The Supris sling and introducers are indicated for the surgical treatment of female stress urinary incontinence (SUI), resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

VI. COMPARISON OF KEY TECHNOLOGICAL CHARACTERISTICS

The purpose of this 510(k) is to request clearance for changes to the polypropylene source and fiber diameter of the mesh sling used in the Altis, Aris and Supris systems. The modified Altis, Aris and Supris devices are substantially equivalent in indications for use, design, target population, sterilization method, biocompatibility, duration of use, and materials to the currently marketed Altis (K221874), Aris (K050148) and Supris (K111233) devices. The changes to the mesh have been evaluated through performance testing and do not raise new questions of safety or effectiveness.

VII. PERFORMANCE DATA

The following test data was provided in support of the substantial equivalence determination and changes to mesh material.

Biocompatibility Testing

Biocompatibility testing was conducted based upon ISO 10993-1 (2018): Biological evaluation of medical devices – Part 1: "Evaluation and testing within a risk management process" and FDA Guidance for Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff (September 2020). Testing was conducted on the Altis sling and is representative for the Aris and Supris slings. All test results were deemed acceptable based on the established specifications and through comparative analysis of the currently marketed Altis sling against the proposed Altis sling.

Performance Testing

Design verification (bench) testing was conducted in support of the substantial equivalence determination and changes to the mesh, and included the recommended evaluations detailed in FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (March 1999):

- Mesh Density
- Mesh Thickness
- Average Pore Size
- Sling Length
- Sling Width
- Length at Sling Ends
- Width at Sling Ends

- Mesh Tensile Strength
- Mesh Elongation at Break
- Mesh Elasticity
- Mesh Stiffness
- Suture Pull-Out Strength
- Mesh Tear Resistance
- Suture/Mesh Weld Strength
- Shelf-life testing to support 3 years (Altis) and 5 years (Aris/Supris)

Sterilization

The Altis Single Incision Sling System, Aris Transobturator Sling System, and Supris Retropubic Sling System are sterilized using ethylene oxide in validated cycles demonstrating a sterility assurance level of 10^{-6}.

Packaging and Distribution

The packaging and distribution data which supported the legally marketed Altis Single Incision Sling System (K221874), Aris Transobturator Sling System (K050148) and Supris Retropubic Sling System (K111233) is still valid. No additional packaging testing was required due to the changes to the mesh.

No animal studies or clinical testing were provided to support substantial equivalence between the subject and predicate devices.

VIII. CONCLUSIONS

The modifications to the mesh used in the Altis Single Incision Sling System, Aris Transobturator Sling System, and Supris Retropubic Sling System have been demonstrated to be substantially equivalent to the primary predicate, Altis Single Incision Sling System (K221874), based on the performance data provided. The Aris Transobturator Sling System is also substantially equivalent to the secondary predicate, Aris Transobturator Sling System (K050148), and the Supris Retropubic Sling System is also substantially equivalent to the tertiary predicate, Supris Retropubic Sling System (K111233). The supporting test results demonstrate that the mesh change for the Altis, Aris and Supris slings do not raise new questions of safety or effectiveness, and the devices are substantially equivalent to the predicates.